This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

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POSITION PAPER:
EPA's Preliminary Human Health Risk Assessment
for Phosalone (OPP-34216)

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I. INTRODUCTION

As part of the preparation of the Reregistration Eligibility Decision (RED) for Phosalone, EPA has reviewed the data package and conducted a preliminary human health risk assessment. The draft RED chapters for chemistry, toxicology, and product chemistry, as well as the human health risk assessment, the acute and chronic dietary assessments, the HIARC report, and the FQPA safety factor committee report were sent to Aventis CropScience (formerly Rhone Poulenc Ag Company or RPAC) on November 5, 1999 by the EPA. The EPA provided a 30-day comment period to afford the registrant an opportunity to comment on errors in these documents, as well as to address Confidential Business Information (CB I) and planned data.

The 30-day response from Aventis CropScience (Aventis) submitted to EPA on December 7, 1999 included a request by Aventis for a meeting with the Agency to discuss issues related to additional field trial requirements specified in the draft RED. This meeting was held on January 6, 2000 and as agreed with the Agency, the highlights of that meeting are reflected in the following comments.

The Residue Chemistry Chapter of the draft RED stated that additional field trial data are required on grapes, apples, pears, cherries, peaches, and plums before the tolerances for phosalone residues in/on these commodities can be assessed. Specifically, the Agency requires:

- Trials in France: 2 on grapes
- Trials in Canada: 3 on apples; 3 on cherries; 3 on peaches; 3 on plums; 2 on grapes; and 2 on pears.

Aventis has recently completed the 2 trials on apples in Canada (Cosgrove, D., 1999. Report No. 99098 DC, MRID 45013401) and 5 trials on cherries (Cosgrove, D., 1999. Report No. 99097 DC, MRID 45013402). Based on the requirements of the Draft *Import Tolerance Guidelines* (U.S.EPA, 1998), the field trial data currently available and those recently completed are more than sufficient to support the proposed import tolerances for phosalone. The *Guidelines* provide detailed instructions on determining the required number of field trials, taking into consideration the percentage of the commodity relative to the US diet and the relative amount imported into the US. Trials need to be conducted in all countries, which export at least 5% of the total amount of a commodity imported in the US. A minimum of 3 trials is required for any crop. In certain cases, fewer trials need to be conducted if there is a low dietary intake of the commodity and if the amount imported is relatively small. The detailed discussions for each crop illustrate that these requirements have been met by phosalone.

The Agency's requirement for additional trials in Canada is based primarily on the higher use rate in Canada as compared to Europe (2.5 x EU rates for apples and for grapes). Results from the recently completed trials in Canada show residues comparable to trials on apples in the EU. Results for cherries showed higher residues in the Canadian trials, but residue levels were well below the current US tolerances for cherries. However, considering the low volume of imports of the above commodities from Canada into the the United States and the very low usage of phosalone in Canada, the potential residues of phosalone on cherries imported from Canada would be very low (<0.1 ppm).

In general, the volume of imported apples, pears, grapes, peaches, and cherries from countries where phosalone is registered is extremely low. The market share of phosalone in those exporting countries is minimal. The Anticipated Residue Estimates Chapter of the draft RED noted that "less than *1.5%* of the apples (fresh and dried), *0.1%* of pears, *0.05%* of peaches, and *0.2%* of plums available in the US are imported from countries with phosalone registrations". The FDA monitoring data for 1992-1998 support these estimates. All imports of apples, pears, grapes and peaches showed non-detectable phosalone residues.

The Residue Chemistry Chapter of the draft RED (p.27) notes the existing Codex MRLs for phosalone on apples, citrus fruit, grapes and potatoes. It should be noted that the 1999 JMPR set Codex MRLs on stone fruit and revised the MRLs on pome fruit and tree nuts, based on the same set of studies as submitted to EPA. The JMPR recommended the following MRLs for phosalone: 2 mg/kg for pome fruit; 2 mg/kg for stone fruit; 0.1 mg/kg for almonds; 0.05 mg/kg for hazelnuts and walnuts.

Therefore, Aventis reiterates its position that the additional data requirements beyond the currently available and recently completed field trial data are unnecessary, given the low market share, low potential for treated imported commodities, and in line with harmonization with Codex MRLs. The following is a discussion that explains this position in detail.

III. RATIONALE SUPPORTING AVENTIS POSITION THAT ADDITIONAL FIELD TRIALS ARE NOT NECESSARY

A. Grapes

The EPA has indicated that the number of grape trials conducted at maximum label rate is insufficient to support the import tolerance. EPA required 2 additional trials in Canada and 2 in France. Aventis has submitted data representing a total of 3 trials from Italy. The main countries having registrations on phosalone are Italy, France, Spain, Portugal and Canada. Fresh market exports from these countries to the US are nominal. The major commodity produced from grapes that is exported from these countries to the US is wine. Agricultural statistics confirm that essentially all imported grapes from countries where phosalone is registered are in the form of juice or wine.

According to Aventis, France is removing uses in/on grapes from the label as of the spring 2000 printing, due to a decline in market share and replacement by other products. Although still registered for use in grapes in Canada, phosalone usage is nominal.

As EPA noted on page 17 of the Residue Chemistry Chapter of the draft RED, "residues in grape juice is not probable as the grape metabolism study shows that phosalone residues are low in grape juice (1.4% TRR)..." Consequently, one would not expect to find detectable residues in wine. The FDA monitoring data, as described below, substantiates this. In fact the Anticipated Residues Chapter of the draft RED, indicated that for grapes (fresh, juice and wine) the FDA monitored a total of 107 samples from the countries with phosalone registrations during the period 1992-1998. During this time *no detectable* phosalone residues were observed in *any* of these samples. Therefore, it is not necessary to generate additional data in support of the use of phosalone on grapes.

B. Pome Fruit

EPA has requested 3 additional trials on apples and 2 additional trials on pears. EPA has stipulated that these trials must be conducted in Canada or the US at l X Canada's GAP. About 27% of the total supply of apples (fresh and processed) in the US were imported in 1992-1998 (USDA 1998). Of these, 4.7% of the apples came from Canada. Following the *Import Tolerance Guidelines*, 12 trials would be needed for apples. Aventis has submitted 15 trials on apples from various European countries which export these crops to the US. Because the imports of apples from Canada account for about 5% of total imported apples, Aventis conducted additional 2 trails on apples in Canada. The trials have been completed and were submitted to EPA (Cosgrove, D., 1999. Report No. 99098 DC, MRID 45013401). Results of these trials showed residues from 0.75 – 1.95 ppm after 3 applications of 500SC phosalone formulation at the rate of 1.5 kg ai/ha and a PHI of 30 days. These residues fall within the same range as the residues obtained from trials in the EU (0.38 mg/kg – 1.5 mg/kg), which used 3 applications of 232EC, 350EC, or 30WP formulations of phosalone at the rate of 0.6 kg ai/ha with a PHI of 14 days in France and 21 days in Italy.

Further, EPA noted on page 5 of the Anticipated Residue Estimates Chapter of the draft RED that "less than *1.5%* of the apples (fresh and dried) available in the US are imported from countries with phosalone registrations. EPA also reported that the FDA monitoring data from 1992-1998 for apples imported from countries with phosalone registrations were generally found to have non-detectable residues. Specifically, of the 88 samples analyzed only 5 samples had detectable residues, the highest of which was 0.2 ppm.

Similarly, about 20% of the supply of pears in the US are imported. Of these, only 0.14% come from Canada. In accordance with the *Import Tolerance Guidelines*, only 3 trials are needed for pears. Aventis has already submitted 4 trials on pears.

In addition, as reported by the EPA, pears imported from countries having phosalone registrations constitutes less than *0.1%* of the available market in the US. The FDA, in

their monitoring program from 1992-1998, analyzed 86 samples from countries having phosalone registrations. Of these 86 samples, *none* were found to have detectable residues.

The 1999 JMPR reviewed the residue data for uses of phosalone in/on apples and pears, and recommended the establishment of a new group MRL for pome fruit, of 2 mg/kg. The data reviewed consisted of the same package submitted to the Agency to support an import tolerance for pome fruit in the US. Although the process of arriving at a recommended MRL or tolerance may differ, a harmonized limit is essential to facilitate international trade.

It is Aventis' contention that no additional data need be generated for phosalone on pome fruit .

III. STONE FRUIT

The Agency has requested 3 additional trials on each of cherries, peaches and plums. EPA has stipulated that these trials must be conducted in Canada or the US at l X Canada's GAP. Imported peaches, plums, and cherries account for about 5%, 8%, and 2%, respectively, of the total supply of these commodities in the US (USDA 1998). Of these, only 0.4% of the peaches, 0.1% of plums, and 7% of cherries came from Canada. Following the *Import Tolerance Guidelines*, 3 trials each would be needed for peaches, plums, and cherries. Aventis has submitted 7 trials on cherries and 4 trials on peaches from various European countries which export these crops to the US. Because the imports of cherries from Canada account for more than 5% of total imported cherries, Aventis conducted additional 5 trails on cherries in Canada. The trials have been completed and were submitted to EPA (Cosgrove, D., 1999. Report No. 99097 DC, MRID 45013402). These five trials on cherries exceed the 3 trials that the EPA has requested and as required by the *Guidelines*. Consequently, the EPA's data request for this commodity has been met.

Regarding peaches, Aventis believes that the required number of trials according to the *Import Tolerance Guidelines* have been met. Further, imports of peaches from Canada are minimal so no trials are needed in Canada. In addition, page 5 of the Anticipated Residue Estimates Chapter of the draft RED noted that "0.05% of peaches available in the US are imported from countries having phosalone registrations". Of the 59 peach samples monitored by the FDA from countries having phosalone registrations, only 1 sample was found to have detectable residues. The residue level in this sample was 0.13 ppm. Aventis believes that no additional trials on peaches should be necessary.

As for plums, the imports are very small (about 2%) and those from Canada are just 0.1% of the total supply in the US. The Anticipated Residue Estimates Chapter of the draft RED noted that "less than 0.2% of the plums (fresh and dried, on fresh basis) available in the US are imported from countries having phosalone registrations. This fact alone should lead the EPA to conclude that residue trials are not needed and that no additional trials should be necessary. However, to support the EPA in making this decision, the following is presented.

While residue data from monitoring or field trials are not available for plums, it is anticipated that the residues would not exceed those observed in/on cherries. The rationale for this is that in examining the field trial data for cherries and peaches one sees that the residues from cherry trials are comparable to the peach trials. Specifically, cherries treated with 2 applications of 0.6 kg ai/ha (total of 1.2 kg ai/ha/season) and having a PHI of 14-17 days are comparable to residues on peaches treated with 3 applications of 0.9 kg ai/ha (total of 2.7 kg ai/ha/season) and having a PHI of 18-26 days. Residue data on plums following the treatment regimen of peaches typically results in comparable residues. Therefore, the available data on peaches and cherries as well as data recently completed on cherries should suffice to support all stone fruit, since the cherry data and peach data are comparable and the plum data would be expected to be comparable with the peach. The 1999 JMPR recommended a group MRL of 2 mg/kg for stone fruits after reviewing 16 trials on cherries and 4 on peaches, concluding, "the residues in cherries and peaches belong to the same population".

Finally, when considering a section 3 registration in the US for a stone fruit group tolerance, 6 trials are required. Of these 6 trials 4 are from region 10 (i.e. California, southern Arizona, and southern New Mexico), a region that produces 90% of the plum market in the US. It is Aventis' position that requesting 3 trials in a case with a *maximum* of 0.2% market share is excessive and onerous. In summary, no additional trials on plums should be required.

It is the position of Aventis that no additional trials are needed to support an import tolerance for stone fruits. It should be noted that as stated earlier, the 1999 JMPR set an MRL of 2 mg/kg for residues of phosalone on stone fruit, from trials on cherries and peaches.

IV. SUMMARY AND CONCLUSION

Aventis believes that the additional field trials in France and Canada, which are required by EPA, are not necessary to support import tolerances of phosalone in/on apples, pears, cherries, peaches, plums and grapes. Based on the requirements of the *Draft Import Tolerance Guidelines* (U.S.EPA, 1998), the field trial data currently available and those recently completed are more than sufficient to support the proposed import tolerances for phosalone. In addition, as noted by the EPA's Anticipated Residue Estimates Chapter of the draft RED, only small amounts of apples, pears, peaches, plums, grapes and cherries (0.05% - 1.5%) of the total supply available in the US come from countries with phosalone registration. The FDA monitoring data show that in general, residues of

phosalone on these imported commodities are non-detectable. This trend is expected to continue as the use of phosalone continues to decline due to shifts to alternative products. Therefore, Aventis maintains that there is no need to generate additional data to support the import tolerances on phosalone.

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